RenMed

DEC 1 4 2001

K013200

NON-CONFIDENTIAL 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pages VI – VIII)

510(k) Summary

Company Information:

Rennels Medical Corp.
203 Northwood Drive
Morganton, NC 28655
(828)437-1085
Contact: David Lee, President

Preparation Date of Summary:

September 20, 2001

Trade Name:

RenMed *Contami-Shield*™ Breathing Circuit Sleeve.

Common Name:

Filter, Bacterial, Breathing Circuit

Product Class/Classification:

Class II, 73CAH, 21CFR 868.5260

Predicate Device:

ARC Medical, Inc., Circuit Guard

Description of the Device:

The *Contami-Shield*™ Breathing Circuit Sleeve, indicated for use with mechanically-ventilated patients, is intended to reduce the gross external contamination of the breathing circuit during use. When used in conjunction with a bacterial/viral breathing filter, the *Contami-Shield* is intended to provide improved protection against contamination of the breathing circuit over a breathing filter alone.

The disclosed device is an external device, not in physical contact with the patient, intended for use with ventilators, anesthesia machines, and open flow systems where the

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external protection of the breathing circuit is desired. The disclosed device shall be slipped over the external surface of the breathing circuit prior to use. A filter or HME filter may be changed or removed from the breathing circuit, while the *Contami-Shield* is present and in use, if desired.

Indications for Use

Indications (from labeling): The *Contami-Shield*™ Breathing Circuit Sleeve, indicated for use with mechanically-ventilated patients, is intended to reduce the gross external contamination of the breathing circuit during use. When used in conjunction with a bacterial/viral breathing filter, the *Contami-Shield* is intended to provide improved protection against contamination of the breathing circuit over a breathing filter alone.

For Single Patient Use.

The device is neither intended to be in contact with the patient nor does it use or impart electrical energy.

Contraindications

The device is not intended for use with breathing circuits equipped with exhalation valves, water traps, nebulizers, or heated wires.

Comparison to Predicate Device

The following table includes the various aspects of the of the *Contami-Guard* Breathing Circuit Sleeve, compared with those of the predicate device:

	RenMed *Contami-Guard*	ARC Medical circuit-Guard
Use		
Intended to provide protection for the breathing circuit against gross exterior contamination.	YES	YES
To be used in conjunction with a bacterial/viral breathing filter to reduce internal and external contamination of the breathing circuit.	YES	YES
Single Patient Use.	YES	YES
Design		
Clear polyethylene/polypropylene sleeve.	YES	YES

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None of the differences noted in the performance specifications for each device are considered clinically significant when the *Contami-Guard* is used as intended.

Relevant Standards

None known.

CONCLUSION

The comparison of the *Contami-Guard* Breathing Circuit Sleeve with the selected predicate device demonstrates that the device is safe and effective for its intended use and is substantially equivalent to the predicate device.

Sincerely,
Rennels Medical Corp.

David Lee
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2001

Mr. David Lee
Rennels Medical Corp.
P.O. Box 3626
Morganton, NC 28680

Re: K013200
RenMed Contami-Shield Breathing Circuit Sleeve
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II (two)
Product Code: 73 CAH
Dated: September 20, 2001
Received: September 25, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

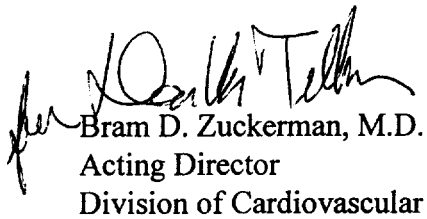
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number, if known:

Device Name: **RenMed *Contami-Guard*™ Breathing Circuit Sleeve, Model 9999/01**

Indications for Use: The *Contami-Shield*™ Breathing Circuit Sleeve, indicated for use with mechanically-ventilated patients, is intended to reduce the gross external contamination of the breathing circuit during use. When used in conjunction with a bacterial/viral breathing filter, the *Contami-Shield* is intended to provide improved protection against contamination of the breathing circuit over a breathing filter alone.

For Single Patient Use.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013200

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)